

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

*KM*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/265,710 03/09/99 BANDMAN

0 PF-0339-1DIV

HM22/0117

LUCY J BILLINGS  
INCYTE PHARMACEUTICALS INC  
3174 PORTER DRIVE  
PALO ALTO CA 94304

EXAMINER

ULM, J

ART UNIT

PAPER NUMBER

1646

*LO*

DATE MAILED:

01/17/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>09/265,710</b>	Applicant(s) <b>Bandman et al.</b>
	Examiner <b>John Ulm</b>	Group Art Unit <b>1646</b>

Responsive to communication(s) filed on Jan 8, 2001

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1, 2, 12-18, 21, 23-35, 40, and 41 is/are pending in the application.

Of the above, claim(s) 13-18, 23-35, 40, and 41 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1, 2, 12, and 21 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1646

- 1) Claims 1, 2, 12 to 18, 21, 23 to 35, 40 and 41 are pending in the instant application. Claims 1, 2, 12 and 21 have been amended, claims 22 and 36 to 39 have been canceled and claim 41 has been added as requested by Applicant in Paper Number 8, filed 22 August of 2000.
- 2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
- 3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 4) Claims 13 to 18, 23 to 35 and 40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.
- 5) Newly submitted claim 41 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claim 41 is drawn to a method of using an antibody that is the subject of invention II in Paper Number 5, which is a nonelected invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 41 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Art Unit: 1646

6) Claims 1, 2, 12 and 21 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, substantial and specific asserted utility or a well established utility for those reasons of record in section 4 of Paper Number 7. Applicant has traversed this rejection on the premise that a "purified human integral membrane protein" of the instant invention can be employed as an osteoblast marker. This is not a credible utility because there is no evidence of record that the disclosed protein is differentially expressed in osteoblasts. At best, the instant specification discloses that the protein described therein is structurally similar to a different protein which is known to be differentially expressed in osteoblasts. There is absolutely no evidence of record that similarity of structure between two proteins is predictive of a similarity in expression pattern of those proteins. Therefore, one of ordinary skill would not conclude that a protein of the instant invention could be employed as a tissue marker based sole on the similarity of that protein to a different protein.

Further, the employment of a protein of the instant invention, or a nucleic acid encoding that protein, as a tissue specific marker is not a substantial or specific utility. All human proteins can invariably be classified into two categories, those which are expressed in a tissue or developmentally specific manner and those which are expressed ubiquitously. It can be alleged that any protein which is expressed in a tissue specific manner can be employed to detect the tissue in which it is expressed in a sample. Alternately, a human protein which is expressed ubiquitously can be employed to detect the presence of any human tissue in a sample. Such

Art Unit: 1646

utilities are analogous to the assertion that a particular protein can be employed as a molecular weight marker, which is neither a specific or substantial utility.

7) Claims 1, 2, 12 and 21 also stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8) Claims 1, 2, 12 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for those reasons of record in section 6 of Paper Number 7. The instant specification does not provide a detailed written description of even one variant" of the single protein which is disclosed in the instant specification. If Applicant is urging that the term "variant" encompasses any protein having at least 90% sequence identity to SEQ ID NO:1 then the presence of this limitation in the claims is redundant and, therefore, confusing. If, on the other hand, these claims are intended only to encompass those proteins which retain functionality **and** have least 90% sequence identity to SEQ ID NO:1 then the instant specification does not provide an adequate written description of this genus of protein since the functional limitation does not inherently flow from the structural limitation and the instant specification does not disclose those structural elements which are definitive of the genus of proteins claimed.

Art Unit: 1646

9) Applicant's arguments filed 22 August of 2000 have been fully considered but they are not persuasive.

10) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800